

Docket No.: 03108/0202223-US0
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Venkateswarlu Jasti et al.

Application No.: 10/519,219

Confirmation No.: 7317

Filed: May 13, 2005

Art Unit: 1626

For: NOVEL TETRACYCLIC ARYLSULFONYL
INDOLES HAVING SEROTONIN RECEPTOR
AFFINITY USEFUL AS THERAPEUTIC
AGENTS, PROCESS FOR THEIR
PREPARATION AND PHARMACEUTICAL
COMPOSITIONS CONTAINING THEM

Examiner: N. Grazier

RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This response to the Office Action dated January 3, 2007 is accompanied by a petition for a two-month extension of time and the requisite fee, extending the period for response to April 3, 2007.

In response to the restriction requirement set forth in the Office Action, Applicants hereby provisionally elect Group I, claims 1-4 and 14 with the variables as defined in the Office Action, for continued examination, with traverse. Applicants further provisionally elect the compound 6-(2-N,N-dimethylaminoethyl)benzo[d]isothiazolo[3,2-a]indol-S,S-dioxide, i.e., a compound of Formula (I) wherein R¹-R¹² are hydrogen, R¹³ and R¹⁴ are a (C₁-C₁₂)alkyl, and n is 1.

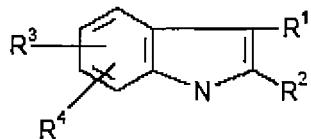
The Examiner has required restriction because the application allegedly lacks unity of invention under PCT Rules 13.1 and 13.2. According to the Examiner, there is no unity of invention because the core structure of Formula (I) is not a unifying criterion and the variables of Formula (I) do not belong to a recognized class of chemical compounds. The Examiner asserts that the core structure of Formula (I) is not a unifying criterion because it is not novel.

However, the Examiner's position is without merit because (1) it confuses the "special technical feature" of Rule 13.2 with the "common structure" described in MPEP § 1850 III.B relating to Markush practice, and (2) the genus of compounds described by formula (I) as claimed in claim 1 is evidenced to be free of the prior art according to the International Search Report issued in the international stage.

(1) "Special Technical Feature". Under PCT Rule 13.2, unity of invention is satisfied when there is a "special technical feature" that defines a contribution over the prior art. In the special case of a single claim defining alternative compounds (a "Markush" claim) the special technical feature is present "when the alternatives are of a similar nature." MPEP § 1850 III.B. Alternatives are of a similar nature when "(A) all alternatives have a common property or activity; and (B)(1) a common structure is present ...; or (B)(2) ... all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains. *Id.* It is not necessary, as the Examiner alleges, that the "common structure" relevant to Markush practice be novel.

The Examiner's attention is directed to the attached PCT International Search and Preliminary Examination Guidelines, pages 84-88 (Exhibit A). Example 18 depicts indole compounds with various substituents at R¹-R⁴ that are useful as pharmaceuticals.

Claim 1: A compound of the formula:



wherein R¹ is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; R²-R⁴ are methyl, benzyl, or phenyl. The compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen.

(Guidelines at p. 84.)

According to the Guidelines, because the indole moiety is a significant structural element shared by the compounds and all the compounds are alleged to possess the same utility, unity of invention is present. The indole moiety does not have to be (and certainly isn't) novel.

In this case the indolyl moiety is the significant structural element that is shared by all of the alternatives. Since all the claimed compounds are alleged to possess the same utility, unity is present.

(Guidelines at p. 84.)

In the subject application, a special technical feature is present because the alternative compounds share a common structure (a tetracyclic arylsulfonyl indole core) and are believed to have serotonin receptor affinity.

(2) Genus of claim 1 is free of prior art. The International Search Report corresponding to the present application does not cite any prior art against claim 1 that would destroy novelty or inventive step. A single "X" reference was cited against claims 24 and 25, which only pertain to intermediates useful in preparing the compounds of formula (I) and which are not taught to possess the same utility as the compounds of formula (I). The Examiner has not provided any evidence or cited any art that suggests the special technical feature according to Markush practice does not define a contribution over the prior art.

Accordingly, Applicants traverse the restriction requirement and request that it be withdrawn and all pending claims be examined.

Dated: April 3, 2007

Respectfully submitted,

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EXHIBIT A

WIPO



PCT/GL/ISPE/1
ORIGINAL: English
DATE: March 11, 2004

WORLD INTELLECTUAL PROPERTY ORGANIZATION GENEVA

PATENT COOPERATION TREATY (PCT)

PCT INTERNATIONAL SEARCH AND PRELIMINARY EXAMINATION GUIDELINES

(Guidelines for the Processing by International Searching and
Preliminary Examining Authorities of International Applications
Under the Patent Cooperation Treaty)

as in force from March 25, 2004

1. This document contains the text, as in force from March 25, 2004, of the PCT International Search and Preliminary Examination Guidelines, established by the International Bureau of WIPO after consultation with the International Searching and Preliminary Examining Authorities under the PCT with a view, in particular, to implementing the amendments of the PCT Regulations which entered into force on January 1, 2004.
2. The Guidelines apply to the processing of international applications filed on or after January 1, 2004. They supersede the PCT International Search Guidelines, as in force from September 18, 1998 (document PCT/GL/IS/1), and the PCT International Preliminary Examination Guidelines, as in force from October 9, 1998 (document PCT/GL/IPE/1), which were published in Special Issues of the *PCT Gazette* Nos. S-06/1998 and S-07/1998, respectively. The text of the present Guidelines is the same (subject to minor editorial changes) as in the provisional version of this document (document PCT/GL/ISPE/1 Prov.2) which has been applicable, in practice, since January 1, 2004.
3. The text will also be published in Special Issue No. S-02/2004 (dated March 25, 2004) of the *PCT Gazette*.

driving the marking device and having a supporting surface for the securing disc element. Unity exists between claims 1 and 2.

10.35 Example 15

Claim 1: Compound A.

Claim 2: An insecticide composition comprising compound A and a carrier.

Unity exists between claims 1 and 2. The special technical feature common to all the claims is compound A.

10.36 Example 16

Claim 1: An insecticide composition comprising compound A (consisting of a₁, a₂...) and a carrier.

Claim 2: Compound a₁.

All compounds A are not claimed in the product claim 2 for reasons of lack of novelty of some of them for instance.

There is nevertheless still unity between the subject matter of claims 1 and 2 provided a₁ has the insecticidal activity that is also the special technical feature for compound A in claim 1.

10.37 Example 17

Claim 1: A chair with a lifting mechanism.

Claim 2: A chair with a mechanical screw lifting mechanism.

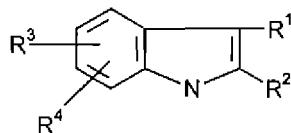
Claim 3: A chair with a hydraulic lifting mechanism.

Unity exists between claims 1-3. The special technical feature common to all the claims is the lifting mechanism. However, if any lifting mechanism is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims.

Markush Practice

10.38 Example 18: Common Structure

Claim 1: A compound of the formula:

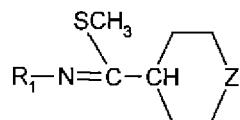


wherein R¹ is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; R²-R⁴ are methyl, benzyl, or phenyl. The compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen.

In this case the indolyl moiety is the significant structural element that is shared by all of the alternatives. Since all the claimed compounds are alleged to possess the same utility, unity is present.

10.39 Example 19: common structure:

Claim 1: A compound of the formula:



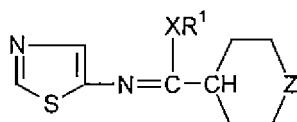
wherein R_1 is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; Z is selected from the group consisting of oxygen (O), sulfur (S), imino (NH), and methylene ($-CH_2-$).

The compounds are alleged to be useful as pharmaceuticals for relieving lower back pain.

In this particular case the iminothioether group $-N=C-SCH_3$ linked to a six atom ring is the significant structural element which is shared by all the alternatives. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

10.40 Example 20: Common Structure

Claim 1: A compound of the formula:

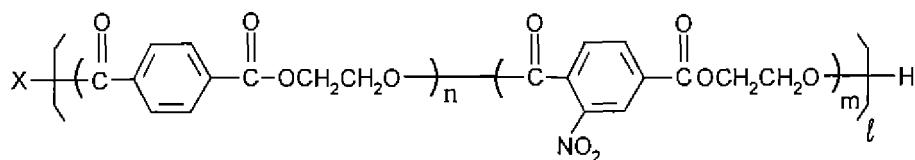


wherein R^1 is methyl or phenyl, X and Z are selected from oxygen (O) and sulfur (S).

The compounds are useful as pharmaceuticals and contain the 1,3-thiazolyl substituent which provides greater penetrability of mammalian tissue which makes the compounds useful as relievers for headaches and as topical anti-inflammatory agents.

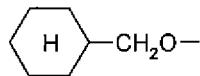
All compounds share a common chemical structure, the thiazole ring and the six atom heterocyclic compound bound to an imino group, which occupy a large portion of their structure. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

10.41 Example 21: Common Structure

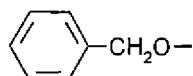


$$1 \leq l \leq 10$$

$$200 \geq n + m \geq 100$$



or

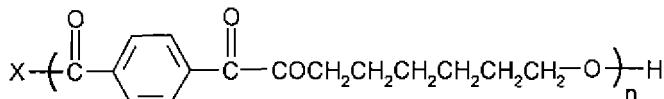


$X:$

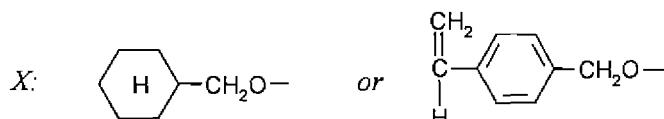
All of the above copolymers have in common a thermal degradation resistance property, due to the reduced number of free COOH radicals by esterification with X of the end COOH radicals which cause thermal degradation.

The chemical structures of the alternatives are considered to be technically closely interrelated to one another. A grouping in one claim is therefore allowed.

10.42 Example 22: Common Structure:



$$100 \geq n \geq 50$$



The compound obtained by esterifying the end COOH radical of known polyhexamethyleneterephthalate with $\text{H}-\text{CH}_2\text{O}-$ has a thermal degradation resistant property, due to the reduced number of free COOH radicals which cause thermal degradation. In contrast, the compound obtained by esterifying the end COOH radical of known polyhexamethyleneterephthalate with a vinyl compound containing a $\text{CH}_2=\text{CH}-\text{CH}_2\text{O}-$ moiety serves as a raw material for a setting resin when mixed with unsaturated monomer and cured (addition reaction).

All esters covered by the claim do not have a property or activity in common. For example, the product obtained through esterification with the "CH₂ = CH" vinyl compound does not have a thermal degradation resistant property. The grouping in a single application is not allowed.

10.43 Example 23: No Common Structure

Claim 1: A herbicidal composition consisting essentially of an effective amount of the mixture of A 2,4-D(2,4-dichloro-phenoxy acetic acid) and B a second herbicide selected from the group consisting of copper sulfate, sodium chlorate, ammonium sulfamate, sodium trichloroacetate, dichloropropionic acid, 3-amino-2,5-dichlorobenzoic acid, diphenamid (an amide), ioxynil (nitrile), dinoseb (phenol), trifluralin (dinitroaniline), EPTC (thiocarbamate), and simazine (triazine) along with an inert carrier or diluent.

The different components under B must be members of a recognized class of compounds. Consequently in the present case a unity objection would be raised because the members of B are not recognized as a class of compounds, but, in fact, represent a plurality of classes which may be identified as follows:

(a) inorganic salts:

copper sulfate
sodium chlorate
ammonium sulfamate

(b) organic salts and carboxylic acids:

sodium trichloroacetate

dichloropropionic acid
3-amino-2,5-dichlorobenzoic acid

(c) amides:

diphenamid

(d) nitriles:

ioxynil

(e) phenols:

dinoseb

(f) amines:

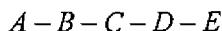
trifluralin

(g) heterocyclic:

simazine

10.44 Example 24

Claim 1: A pharmaceutical compound of the formula:



wherein:

A is selected from C₁-C₁₀ alkyl or alkenyl or cycloalkyl, substituted or unsubstituted aryl or C₅-C₇ heterocycle having 1-3 heteroatoms selected from O and N;

B is selected from C₁-C₆ alkyl or alkenyl or alkynyl, amino, sulfoxy, C₃-C₈ ether or thioether;

C is selected from C₅-C₈ saturated or unsaturated heterocycle having 1-4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

D is selected from B or a C₄-C₈ carboxylic acid ester or amide; and

E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl, pyridyl, or oxazolyl.

From the above formula no significant structural element can be readily ascertained and thus no special technical feature can be determined. Lack of unity exists between all of the various combinations. The first claimed invention would be considered to encompass the first mentioned structure for each variable, that is, A is C₁ alkyl, B is C₁ alkyl, C is a C₅ saturated heterocycle having one O heteroatom, D is C₁ alkyl, and E is a substituted phenyl.

10.45 Example 25

Claim 1: Catalyst for vapor phase oxidation of hydrocarbons, which consists of (X) or (X+a).

In this example (X) oxidizes RCH₃ into RCH₂OH and (X+a) oxidizes RCH₃ further into RCOOH.

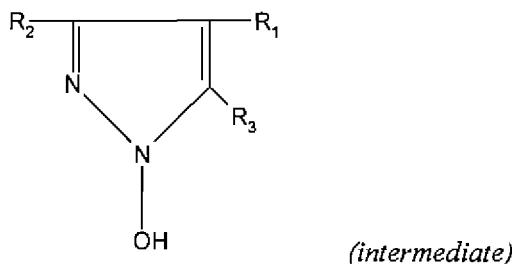
Both catalysts share a common component and a common activity as oxidation catalyst for RCH₃. With (X+a) the oxidation is more complete and goes until the carboxylic acid is formed but the activity still remains the same.

A Markush grouping is acceptable in this case.

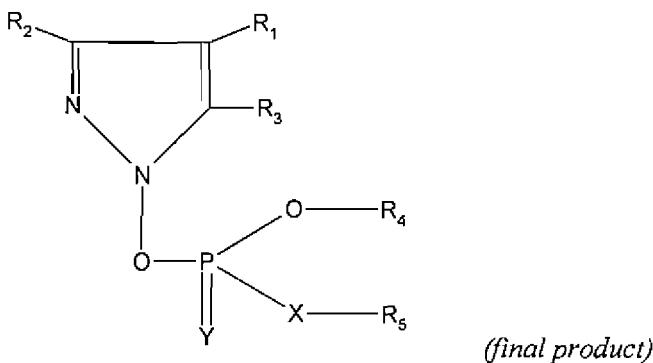
Intermediate/Final Product

10.46 Example 26

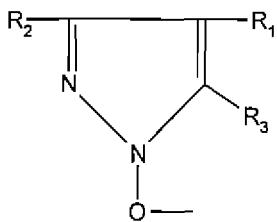
Claim 1:



Claim 2:



The chemical structures of the intermediate and final product are technically closely interrelated. The essential structural element incorporated into the final product is:



Therefore, unity exists between claims 1 and 2.